National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue S.W.
Suite 729-D
Washington, D.C. 20201

Submitted electronically at: https://www.healthit.gov/standards-advisory/draft-2017

Re: Draft 2017 Interoperability Standards Advisory

Dear Dr. Washington,

Thank you for this opportunity to comment on the Draft 2017 Interoperability Standards Advisory.

As you know, Epic is an electronic health records (EHR) developer based in Verona, Wisconsin. Our interoperability and industry standards experiences, as well as our broad experience developing a sophisticated EHR and supporting the healthcare organizations that use it, inform the suggestions we make attached to this letter.

Epic participates in industry standards development in order to further interoperability efforts, including Health Level 7 (HL7), Integrating the Healthcare Enterprise (IHE), National Council for Prescription Drug Programs (NCPDP), Standards & Interoperability Framework, and others. Epic staff have also chaired several HL7 and IHE committees. In addition to developing and implementing standards, we've taken a leadership role in the industry in interoperability governance. In February 2014, we helped to co-found The Sequoia Project's Carequality (www.carequality.org) initiative, which aims to go a step beyond the eHealth Exchange to allow members of different exchange networks, such as Epic's Care Everywhere network, the eHealth Exchange, CommonWell, and public HIEs, to interoperate freely with one another. We also are a supporting member of The Sequoia Project (fka Healtheway), which provides standards, rules, and a directory to power nationwide record sharing on the eHealth Exchange network.

Sincerely,

Peter DeVault
Epic

General Comments

We appreciate the incorporation of feedback from previous years and the opportunity to continue to contribute to the selection of interoperability standards. We agree that most of the standards proposed are appropriate for facilitating interoperability, and we've commented only in places where we disagree or have additional input.

We note that the standards identified are at various stages of implementation and adoption. Users of the Standards Advisory will need to account for appropriate implementation timelines for their particular purpose.

One general comment is that fitness of a standard should be determined within the context of specific use cases and their expected outcomes. We have noted in the relevant subsections several items that could use such clarification.

In several sections, Fast Healthcare Interoperability Resources (FHIR) is listed as the implementation standard. We recommend that the Standards Advisory reference specific FHIR profiles for each appropriate need to eliminate variability and provide a clear path for implementation. This would support the overall direction of the Standards Advisory to address specific interoperability needs by including specific implementation guides and standards. In addition, the ISA should indicate for each profile whether any future versions of the profile may be considered because the FHIR standard is rapidly developing and might at times have incompatible changes. See the specific comments below for each interoperability need that references the FHIR standard.

Purpose

The ISA's stated purpose of providing the industry with a "single, public list of the standards and implementation specifications that can best be used to fulfill specific clinical health information interoperability needs" seems reasonable, though we observe that the purpose seems focused on U.S. industry specifically, and it might be helpful to clarify your intent since there are other considerations for international use cases and standards adoption.

Comments on Informative Characteristics

#2: Implementation Maturity

We are not certain we would be able to use the definitions given to establish whether standards are being piloted or in production use. These categories are separate and not mutually exclusive concepts because a standard could be both in production and in a pilot stage. If the intent is for these categories to be mutually exclusive, it would be helpful to include a threshold for when a

standard exceeds use on a "limited scale" and can be considered to be used in "Production." ONC should also clarify how this would differ from the Adoption Level characteristic.

#3: Adoption Level

The adoption level system would be a more reliable and consistent metric if it was informed by quantitative data about the rate of implementation. Again, perhaps collapsing implementation maturity and adoption level would simplify things.

Comments on Proposed Standards

I-A: Allergies

The findings presented at HL7 ("DoD Allergen Terminology Usage Analysis") based on analysis of Department of Defense, Veterans Affairs, and broad Cerner data sets of patient allergy documentation appear to indicate that a small set (about 400) of existing SNOMED CT and RxNorm IN/MIN codes can cover nearly all relevant allergens that are currently captured in EMRs. These findings further indicate that if minor enhancements are made to these two code sets, using additional code sets such as NDF-RT, UNII, and other RxNorm categorizations might not be necessary. Focusing on these two code sets has potential benefits for improving accurate user entry of data and supporting medical decision-making, as well as improving interoperability.

Interoperability Need: Representing Patient Allergic Reactions

We recommend removing the SNOMED CT Problem Value Set (OID 2.16.840.1.113883.3.88.12.3221.7.4) from the Applicable Value Set(s) & Starter Set(s) section because it is overly broad and largely irrelevant to this interoperability need. Because the value set includes over 16,000 codes representing signs, symptoms, and defined conditions, such as 27495004-AA amyloidosis, it does not functionally limit terms to allergic and adverse reactions. Instead, we recommend using NHSNAdverseReactionCode (OID 2.16.840.1.114222.4.11.3193 limit) because it limits terms to allergic and adverse reactions, such as "fever," "hives," and "swelling." This value set is also a subset of SNOMED codes.

I-B: Encounter Diagnosis

Interoperability Need: Representing Patient Dental Encounter Diagnosis

ONC should add SNOMED CT and ICD-10 as options for the standards/implementation specifications because of the higher rate of adoption across the industry. In our experience, healthcare organizations with integrated medical and dental systems are already using ICD-10 to code the patient dental encounter diagnosis for claims and are unlikely to also use SNODENT. This is primarily because many diagnosis content vendors have not yet included SNODENT as a code set.

I-C: Family Health History

Family Health History includes the interoperability needs "Representing Family Health History" and "Representing Patient Family Health History Observations," but the distinction between them is not clear. ONC should clarify these two use cases and their differences.

Interoperability Need: Representing Patient Family Health History

We agree with ONC's assertion that "some details around family genomic health history may not be captured by SNOMED CT." There is also ongoing discussion in the industry on whether this

standard needs to be extended to add consent information, such as when family member A is reporting information about family member B and whether family member B has consented to the sharing of this information. ONC should continue to track these considerations in the ISA.

I-D: Functional Status/Disability

Interoperability Need: Representing Patient Functional Status and/or Disability

Based on the title of this interoperability need, there is no indication of what kind of data is expected, how it will be used, or what the outcome should be. ONC should clarify the specific use case and expected outcomes for this interoperability need.

I-F: Imaging (Diagnostics, Interventions, and Procedures)

Interoperability Need: Representing Imaging Diagnostics, Interventions, and Procedures

The broad title of this interoperability need seems to have a much larger scope of imaging activities than what the proposed LOINC and DICOM standards might support. ONC should clarify the specific use case and expected outcomes for this interoperability need.

I-L: Nursing

Interoperability Need: Representing Outcomes for Nursing

We need more information about this interoperability need to assess whether the proposed LOINC standard will appropriately capture the information. Depending on the intended scope, LOINC might not be specific enough to capture outcomes.

Interoperability Need: Representing Nursing Interventions and Observations (Observations are Assessment Items)

The boundary between this interoperability need and the interoperability need "Representing Nursing Interventions" is not clear. Also, "Representing Nursing Interventions" uses both LOINC and SNOMED CT, but "Representing Nursing Interventions and Observations" uses only SNOMED CT. To evaluate whether these standards are sufficient, we need more information about the expected outcomes and how these interoperability needs interact.

I-R: Gender Identity, Sex, and Sexual Orientation

Interoperability Need: Representing Patient Sex (At Birth)

In the ONC value set referenced in the Application Value Set(s) section that is a combination of the HL7 V2 Standard value set for Administration Gender and NullFlavor, we recommend adding a value for "Left Unassigned" or "Not Recorded" to indicate cases where clinicians do not assign a sex at birth.

Interoperability Need: Representing Patient-Identified Sexual Orientation

We note that the Health Information Technology Standards Committee (HITSC) has called for national discussion on the appropriate manner to store this information. The outcome of this discussion should inform the vocabulary sets and define an appropriate value set for this interoperability need. For example, "asexual" is a value that is commonly used and is missing from the Starter Set you recommend. "Asexual" should be added to the Starter Set in the ISA for this interoperability need.

As this section is currently written, under the header "Patient-Identified Sexual Orientation", we are uncertain if the intent is that the value set listed under "Applicable Value Set(s) and Starter Set(s)" would be how the patient identifies their sexual orientation or a set of values to map how a patient identifies their sexual orientation for the purposes of interoperability.

Generally we think the best role for the ISA is to focus on interoperability and not on how patients or clinicians interact with software, so the best focus would be to identify how concepts should be expressed between systems.

The term UNK should be used by a system to represent that a value exists but is not able to be mapped to any of the other terms in the value set. UNK would not be appropriate to be used to indicate that the patient lacks surety or is confused regarding their orientation. Instead, we recommend using the term ASKU.

I-U: Unique Device Identification

Interoperability Need: Representing Unique Implantable Device Identifiers

ONC could include several interoperability needs within the I-U: Unique Device Identification section to more granularly capture the use cases within this section with a level of specificity comparable to the other sections. We suggest adding the following interoperability needs:

- Defining a Globally Unique Device Identifier. This need should use the Unique Device Identifier standard as defined by the Food and Drug Administration that is currently identified.
- Transmitting a Unique Device Identifier. This need should use the HL7 Harmonization Pattern for Unique Device Identifiers standard that is currently identified.
- Registering and Tracking Patient Device Identifiers. This need should use the GUDID database and interface specifications when they are finalized by the FDA.

II-A: Admission, Discharge, and Transfer

Interoperability Need: Sending a Notification of a Patient's Admission, Discharge, and/or Transfer Status to the Servicing Pharmacy

The hospitals and pharmacies that we work with have not expressed this need, and we request more information about this use case. We recommend that the HL7 Version 2 Patient Administration transaction set be adopted as an alternative to the NCPDP SCRIPT Standard for Sending a Notification of a Patient's Admission, Discharge, and/or Transfer Status to the Servicing Pharmacy. The HL7 Patient Administration transaction set already has a high level of maturity and adoption in hospital settings.

II-C: Clinical Decision Support

Interoperability Need: Provide Access to Appropriate Use Criteria

The FHIR standard is rapidly evolving with non-backward compatible changes being added with every new version. ONC should clarify in the Limitations, Dependencies, and Preconditions for Consideration section whether the referenced version of the HL7 FHIR Implementation Guide is expected to evolve with future versions of the base FHIR specifications, such as from DSTU 2 to STU 3 and beyond. Clarifying version expectations will help implementers to prepare accordingly for future changes.

II-H: Electronic Prescribing

Interoperability Need: A Prescriber's Ability to Create a New Prescription to Electronically Send to a Pharmacy

The third bullet point in the Limitations, Dependencies, and Preconditions for Considerations section should be removed because this functionality applies to the Interoperability Need: Pharmacy Notifies Prescriber of Prescription Fill Status instead.

Interoperability Need: Allows the Pharmacy to Respond to Prescriber with a Change on a New Prescription

The first bullet point in the Limitations, Dependencies, and Preconditions for Considerations section should be revised from the "RX message" to the "RxChange transaction" instead to more accurately represent this functionality.

You requested feedback on the adoption level of the RxChange transaction. As RxChange is a new requirement as part of the 2015 ONC Certification and major pharmacy networks are still rolling out their support, we believe today's adoption of the RxChange transaction in production environments is low. We anticipate a significant increase in adoption over the next two years.

Interoperability Need: Cancellation of a Prescription

You requested feedback on the adoption level of the Cancel transaction. As the Cancel transaction is a new requirement as part of the 2015 ONC Certification and major pharmacy networks are still rolling out their support, we believe today's adoption of the Cancel transaction in production environments is low. We anticipate a significant increase in adoption over the next two years.

Interoperability Need: Pharmacy Notifies Prescriber of Prescription Fill Status

You requested feedback on the adoption level of the Fill transaction. As the Fill transaction is a new requirement as part of the 2015 ONC Certification and major pharmacy networks are still rolling out their support, we believe today's adoption of the Fill transaction in production environments is low. We anticipate a significant increase in adoption over the next two years.

Interoperability Need: Allows Prescriber to Respond to a Prior Authorization for a Medication Electronically to the Payer/Processor and Prior Authorization Cancel Request

The two interoperability needs for responding to a prior authorization and for prior authorization cancel requests should be combined into a single interoperability need. Organizations need to implement all parts of the implementation standards for both sections to support electronic prior authorization, and the workflow cannot be completed without full implementation. We recommend consolidating these sections into a single interoperability need called "Allows Prescriber to Electronically Request Prior Authorization for Medications."

Also, the implementation specification should be updated from NCPDP SCRIPT Version 10.6 to NCPDP SCRIPT Version 2013101. Electronic prior authorization transactions were not available in Version 10.6 but were first released in version 2013101, which is the standard used by the industry today.

II-L: Medical Device Communication to Other Information Systems/Technologies

ONC should add a second interoperability need to this section because there is a distinctly separate use case for implantable device readings. For example, the IHE-IDCO implementation specification is growing in adoption for implantable cardiac devices and has been proven to serve a need for caregivers and patients by giving patients more information about their implantable devices. We encourage ONC to include more standards and implementation specifications as they relate to implantable device readings.

Interoperability Need: Transmitting Implantable Device Readings

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-IDCO (Patient Care Device Profiles)	Final	Production	●●○○○	No	Free	N/A

II-O: Public Health Reporting

Interoperability Need: Reporting Cancer Cases to Public Health Agencies

The HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm should be marked Yes for test tool availability because it can be tested using the NIST tool.

Additionally, we note that the FHIR standard is rapidly evolving with non-backward compatible changes being added with every new version. ONC should clarify in the Limitations, Dependencies, and Preconditions for Consideration section whether the referenced version of the HL7 FHIR Implementation Guide is expected to evolve with future versions of the base FHIR specifications, such as from DSTU 2 to DSTU 3 and beyond. Clarifying version expectations will help implementers to prepare accordingly for future changes.

Interoperability Need: Case Reporting to Public Health Agencies

The Limitations, Dependencies, and Preconditions for Considerations section includes reporting for specialized registries using the Early Hearing Detection and Intervention (EHDI) and Office of Population Affairs (OPA) Family Planning Reporting IHE Profile. Reporting for specialized registries should be included as a separate interoperability need that is distinct from more general case reporting and that uses these standards. Having an additional interoperability need aligns with your plans to include other forms of reporting, such as Critical Congenital Heart Defects (CCHD), Newborn Lab Screening, Birth and Fetal Death Reporting Enhanced (BFDR-E), and Vital Records Death Reporting (VRDR).

Additionally, we note that the FHIR standard is rapidly evolving with non-backward compatible changes being added with every new version. ONC should clarify in the Limitations, Dependencies, and Preconditions for Consideration section whether the referenced version of the HL7 FHIR Implementation Guide is expected to evolve with future versions of the base FHIR specifications, such as from DSTU 2 to DSTU 3 and beyond. Clarifying version expectations will help implementers to prepare accordingly for future changes.

II-P: Representing Clinical Health Information as a "Resource"

Interoperability Need: Representing Clinical Health Information as a "Resource"

The base FHIR specification referenced here is too broad to be useful. Instead, the ISA should indicate a specific profile or profiles as the implementation guides for this purpose. We recommend referencing the profiles created by the Argonaut project. Argonaut has created 13 implementation guides to specify how to implement the FHIR resources that align with the criteria in 2015 ONC Certification to provide an API. Referencing the appropriate implementation guide would help clarify the intent of the interoperability need and facilitate consistent implementation. For example, the Argonaut guides define required elements and code sets, such as using SNOMED CT for problems and LOINC for lab results.

II-Q: Research

Interoperability Need: Submission of Analytic Data to FDA for Research Purposes

We recommend expanding this interoperability need to more generally address the submission of data for research purposes, regardless of the recipient. If there are specific FDA requirements that this interoperability need intends to address, it would be helpful to include links to specific FDA requirements in the Limitations, Dependencies, and Preconditions for Considerations section.

Interoperability Need: Pre-population of Research Forms from Electronic Health Records

In the Standard/Implementation Specification section, IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation appears to be listed twice (fourth and fifth rows). We assume this is a typographical error.

Additionally, we note that the FHIR standard is rapidly evolving with non-backward compatible changes being added with every new version. ONC should clarify in the Limitations, Dependencies, and Preconditions for Consideration section whether the referenced version of the HL7 FHIR Implementation Guide is expected to evolve with future versions of the base FHIR specifications, such as from DSTU 2 to DSTU 3 and beyond. Clarifying version expectations will help implementers to prepare accordingly for future changes.

Interoperability Need: Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving FDA's Requirements

Two use case sections are labeled with this interoperability need. The second section should be renamed to accurately reflect the intended use case. If the same interoperability need is being met by both sets of standards, it should be denoted in the Limitations, Dependencies, and Preconditions for Consideration section.

Also, it would be helpful to include links to the specific FDA requirements that this interoperability need is intended to meet in the Limitations, Dependencies, and Preconditions for Considerations section.

We also note that IHE-CPRC (Clinical Research Process Content) is listed as an implementation specification. We assume this is a typographical error and intended to be IHE-CRPC.

Interoperability Need: Submit Adverse Event Report from an Electronic Health Record to Drug Safety Regulators

IHE-CPRC (Clinical Research Process Content) is listed as an implementation specification. We assume this is a typographical error and intended to be IHE-CRPC. However, this implementation specification does not currently support adverse events, and we are uncertain how it applies to this interoperability need.

III-A: "Push" Exchange

Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Individuals and Systems

Because FHIR should be treated as a content and structure standard, the use of the base FHIR specification here is confusing. Multiple transports and exchange patterns can be used with FHIR resources. While portions of the FHIR specification (e.g. FHIR Messaging, FHIR Subscriptions, and FHIR Services) may be relevant to a "push" exchange pattern, the sharing of FHIR resources is best described in specific profiles because there is no "one-size-fits-all" implementation of FHIR-related transport. Unless there is a specific transport mechanism that all EHR implementations must support, we recommend removing FHIR as a standard for this interoperability need.

III-D: Healthcare Directory, Provider Directory

Interoperability Need: Listing of Providers for Access by Potential Exchange Partners

The base FHIR specification referenced here is too broad to be useful. Instead, the ISA should indicate a specific profile or profiles as the implementation guides for this purpose. We recommend referencing the profiles created by the Argonaut project. Argonaut has created 13 implementation

guides to specify how to implement the FHIR resources that align with the criteria in 2015 ONC Certification to provide an API. Referencing the appropriate implementation guide would help clarify the intent of the interoperability need and facilitate consistent implementation. For example, the Argonaut guides define required elements and code sets, such as using SNOMED CT for problems and LOINC for lab results.

Questions

General

2 – The table beneath the standards and implementation specifications includes limitations, dependencies, and preconditions. Given the enhancements made, please comment on accuracy and completeness and where information gaps remain, forward applicable content.

> The Applicable Security Patterns for Consideration in Section II are redundant across many different interoperability needs because the patterns are applied at a much higher architectural level than the individual interoperability needs presented here. We suggest collecting this information in Appendix 1 so that the appendix goes beyond listing security standards to actually describe the patterns as they apply to different integration groups (e.g. intra-network messaging versus external messaging, MLLP versus SOAP). Moving all of security pattern information to a single appendix would increase clarity and reduce duplicated content.

Section I: Vocabulary/Code Set

8 – For subsection I-H: Industry and Occupation, there continues to be varied opinion on the standards or implementation specifications to be sited in these areas. Please review and provide feedback on what should be included and/or whether these areas should be removed.

> We understand that public health registries request industry and occupation information. However, there isn't yet agreement on the appropriate level of granularity to capture this data. We recommend that ONC look to the HL7 Occupational Data for Health Project as an opportunity to grow consensus.

9 – For subsection I-R: Sexual Orientation and Gender Identity, Interoperability Need: Representing patient sex (at birth), what are the appropriate genetic identifiers or gender determinants (e.g., gonadal sex, karyotype sex) for potential inclusion in the ISA.

> We called out specific thoughts in the comments above.

Section II: Content/Structure

13 – For the existing interoperability need, "representing clinical health information as a resource", public comments expressed this may not be the best language to describe this area. Please provide feedback on whether or not this is correct or recommend alternative language that better describes this interoperability need.

> We think that the "Representing Clinical Health Information as a 'Resource'" interoperability need is intended to align with the criteria in the 2015 ONC Certification to

provide an API. However, because of the broad terminology, it is difficult to ascertain the use case and whether the proposed standard is sufficient to meet it. Referencing the entire FHIR, DSTU 2 standard instead of a particular profile (as is done in II-C: Clinical Decision Support) makes it difficult to pinpoint what information is intended to be captured and transmitted. We suggest renaming this interoperability need "Application Access Through APIs" to more clearly describe the use case and to use consistent terminology with similar requirements for other programs.

14 – Opinions vary in the way (messaging vs. transport) the ISA should represent FHIR. Please review and provide feedback on the manner FHIR should be represented.

The ISA should represent FHIR as a content and structure standard. FHIR resources can be shared via multiple transport methods, which are commonly found in specific FHIR profiles. By specifying FHIR profiles, the ISA can more precisely communicate the intended use case and how it satisfies the interoperability need.